NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* 1st as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Arizona Administrative Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1.	Sections Affected	Rulemaking Action
	R4-23-110	Amend
	R4-23-704	Repeal
	R4-23-706	Repeal
	R4-23-707	Repeal
	R4-23-708	Repeal
	R4-23-709	Repeal

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. § 32-1904(A)(1).

Implementing statutes: A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3).

3. The effective date of the rules:

March 3, 1999

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 3 A.A.R. 328, January 31, 1997.

Notice of Rulemaking Docket Opening: 3 A.A.R. 1990, July 25, 1997.

Notice of Proposed Rulemaking: 4 A.A.R. 2002, July 31, 1998.

Notice of Termination of Rulemaking: 4 A.A.R. 3006, October 16, 1998.

Notice of Rulemaking Docket Opening: 4 A.A.R. 3046, October 16, 1998.

Notice of Proposed Rulemaking: 4 A.A.R. 3080, October 23, 1998.

5. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name:

Dean Wright, Compliance Officer

Address:

Board of Pharmacy

Board of Pharmacy

5060 North 19th Avenue, Suite 101

Phoenix, Arizona 85015

Telephone:

(602) 255-5125, Ext. 131

Fax:

(602) 255-5740

6. An explanation of the rule, including the agency's reasons for initiating the rule:

The rulemaking repeals the Sections R4-23-704, R4-23-706, R4-23-707, R4-23-708, and R4-23-709. These Sections establish requirements for medical facilities in industrial and business organizations. The present rules were last amended more than 20 years ago and the need for Board of Pharmacy oversight no longer exists. Because of a lack of staff, the Board has not actively enforced these rules in more than 10 years. The rule amends Section R4-23-110 by striking the following definitions: "first-aid stations", "industrial medical stations", "occupational health", and "industrial medicine". These definitions are only used in the Sections being repealed and are no longer necessary.

The Board believes the repeal of these rules will relieve affected businesses from burdensome and outdated recordkeeping requirements without compromising public health and safety. Existing statutes and rules governing the practice of the health professionals (physicians, physician assistants, registered nurse practitioners, and registered nurses) serving these businesses are sufficient to protect the public health. The Board further believes that regulation and enforcement are not necessary to protect the public health when drugs are supplied by health professionals in the work environment.

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Notices of Final Rulemaking

7. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

9. The summary of the economic, small business, and consumer impact:

The proposed rulemaking is exempt from writing an economic, small business, and consumer impact statement under A.R.S. § 41-1055(D)(3).

- 10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

 There are no changes between the proposed rules and the final rules.
- 11. A summary of the principal comments and the agency response to them:

No comments were received by the agency.

- 12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

 Not applicable.
- 13. <u>Incorporations by reference and their location in the rules:</u>
 None.
- 14. Was this rule previously approved as an emergency rule?

 No.
- 15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section

R4-23-110. Definitions

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS

R4-23-704.	Requirements for Medical Facilities in Industrial
	and Business Organizations Repealed
R4-23-706.	Purchasing and Obtaining Drugs Repealed
R4-23-707.	Limitation of Acts Permitted Repealed
R4-23-708.	Proprietary Drugs Repealed
R4-23-709.	Notice of Location and Inspection Repealed
14	ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

"Active ingredient" means any component that furnishes pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or that affects the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug, that are present in the finished drug product in a modified form, and that furnish the specified activity or effect.

"Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

"AZPLEX" means an Arizona pharmacy law examination written and administered by the Board staff or a Board-approved national pharmacy law examination written and administered in cooperation with NABP.

"Batch" means a specific quantity of drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

"Beyond-use date" means a date determined by a pharmacist and placed on a prescription label at the time of dispensing to indicate a time beyond which the contents of the prescription are not recommended to be used.

"Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, consistent with National Sanitation Foundation (NSF) standards, published in the National Sanitation Foundation Standard 49, Class II (Laminar Flow) Biohazard Cabinetry, NSF International P. O. Box 130140, Ann Arbor, MI, revised June 1987 edition, (and no future amendments or editions), incorporated by reference and on file with the Board and the office of the Secretary of State.

"Class 100 environment" means an atmospheric environment in compliance with the Federal Standard 209 Clean Room and Work Station Requirements: Controlled Environment, publication FED-STD-209D, U.S. Government Services Administration 450 Golden Gate Avenue, San Francisco, CA, June 15, 1988 edition which includes January 28, 1991, changes, (and no future amendments or editions), incorporated by reference and on file with the of the Secretary of State.

"Community pharmacy" means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited service pharmacy.

"Component" means any ingredient used in compounding or manufacturing drugs in dosage form, including an ingredient that may not appear in the finished product.

"Container" means:

A receptacle, as described in the official compendium or the federal act, that is used in manufacturing or compounding a drug or in distributing, supplying, or dispensing the finished dosage form of a drug; or

A metal receptacle designed to contain liquefied or vaporized compressed medical gas and used in manufacturing, transfilling, distributing, supplying, or dispensing a compressed medical gas.

"Correctional facility" has the same meaning as in A.R.S. §§ 13-2501 and 31-341.

"Current good compounding practices" means the minimum standards for methods used in, and facilities or controls used for, compounding a drug to ensure that the drug has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Current good manufacturing practice" means the minimum standard for methods used in, and facilities or controls used for manufacturing, processing, packing, or holding a drug to ensure that the drug meets the requirements of the federal act as to safety, and has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Cytotoxic" means a pharmaceutical that is capable of killing living cells.

"Day" means a calendar day unless otherwise specified.

"Delinquent license" means a pharmacist or intern license the Board suspends for failure to renew or pay all required fees on or before the date the renewal is due.

"Drug sample" means a unit of a prescription drug that a manufacturer provides free of charge to promote the sale of the drug. No person shall sell, purchase, or trade or offer to sell, purchase, or trade a drug sample.

"Extreme emergency" means the occurrence of a fire, water leak, electrical failure, public disaster, or other catastrophe constituting an imminent threat of physical harm to pharmacy personnel or patrons.

"FDA" means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for foods, drugs, cosmetics, and other consumer products

"First aid stations" means units within a business or industrial organization which are limited to, as the name implies, first aid treatment of injuries incurred in association with the business function.

"Inactive ingredient" means any component other than an "active ingredient" present in a drug.

"Industrial medical stations" means units where drugs are stored, established within businesses and industrial organizations.

"Internal test assessment" means performing quality assurance or other procedures necessary to ensure the integrity of a test.

"Limited-service correctional pharmacy" means a limitedservice pharmacy, as defined in A.R.S. § 32-1901, that:

Holds a current Board permit under A.R.S. § 32-1931; Is located in a correctional facility; and

Uses pharmacists, interns, and support personnel to compound, produce, dispense, and distribute drugs.

"Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United

States mail, a common or contract carrier, or a delivery service

"Limited-service nuclear pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and provides radiopharmaceutical services.

"Limited-service pharmacy permittee" means a person who holds a current limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long term care facility.

"Lot" means a batch or any portion of a batch of a drug, or if a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures it uniformity. In either case, a lot is identified by a distinctive lot number and has uniform character and quality with specified limits.

"Lot number" or "control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the compounding or manufacturing, control, packaging, and distribution of a batch or lot of a drug can be determined.

"Materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

"Mediated instruction" means information transmitted via intermediate mechanisms such as audio or video tape or telephone transmission.

"NABP" means National Association of Boards of Pharmacy.

"NABPLEX" means National Association of Boards of Pharmacy Licensure Examination.

"NAPLEX" means North American Pharmacist Licensure Examination.

"Occupational Medicine" or "Industrial Medicine" means the field of medicine dealing with the medical conditions associated with persons employed in any occupation.

"Outpatient" means a person who is not a residential patient in a health care institution.

"Outpatient setting" means a location that provides medical treatment to an outpatient.

"Patient profile" means a readily retrievable, centrally located information record that contains patient demographics, allergies, and medication profile.

"Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes, related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process, by identifying and resolving or preventing potential and actual drug-related problems.

"Pharmacy law continuing education" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations, offered by an Approved Provider.

"Prepackaged drug" means a drug that is packaged in a frequently prescribed quantity, labeled in compliance with A.R.S. §§ 32-1967 and 32-1968, stored, and subsequently dispensed by a pharmacist or a graduate intern or pharmacy intern under the supervision of a pharmacist, who verifies at the time of dispensing that the drug container is properly labeled_in compliance with A.R.S. § 32-1968, for the patient.

"Provider pharmacist" means a pharmacist who supplies medication to a long term care facility and maintains patient profiles.

"Radiopharmaceutical" means any drug that emits ionizing radiation and includes:

Any nonradioactive reagent kit, nuclide generator, or ancillary drug intended to be used in the preparation of a radiopharmaceutical, but does not include drugs such as carbon-containing compounds or potassium-containing salts, that contain trace quantities of naturally occurring radionuclides; and

Any biological product that is labeled with a radionuclide or intended to be labeled with a radionuclide.

"Radiopharmaceutical quality assurance" means the performance and interpretation of appropriate chemical, biological, and physical tests on radiopharmaceuticals to determine the suitability of the radiopharmaceutical for use in humans and animals. Radiopharmaceutical quality assurance includes internal test assessment, authentication of product history, and appropriate record retention.

"Radiopharmaceutical services" means procuring, storing, handling, compounding, preparing, labeling, quality assurance testing, dispensing, distributing, transferring, record-keeping, and disposing of radiochemicals, radiopharmaceuticals, and ancillary drugs. Radiopharmaceutical services include quality assurance procedures, radiological health and safety procedures, consulting activities associated with the use of radiopharmaceuticals, and any other activities required for the provision of pharmaceutical care.

"Red C stamp" means a device used with red ink to imprint an invoice with a red letter C at least 1 inch high, to make an invoice of a Schedule III through IV controlled substance, as defined in A.R.S. § 36-2501, readily retrievable, as required by state and federal rules.

"Remodel" means to structurally alter the pharmacy area or location.

"Remote drug storage area" means an area that is outside the premises of the pharmacy, used for the storage of drugs, locked to deny access by unauthorized persons, and secured against the use of force.

"Resident" means a person admitted to and residing in a long term care facility.

"Score transfer" means the process that enables an applicant to take the NAPLEX in a jurisdiction and be eligible for licensure by examination in other jurisdictions.

"Sterile pharmaceutical product" means a dosage form free from living micro-organisms.

"Strength" means:

The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis); or

The potency, that is, the therapeutic activity of a drug substance as indicated by bioavailability tests or by controlled clinical data (expressed, for example, in terms of unity by reference to a standard).

"Supervision" means a pharmacist shall be present, assume legal responsibility, and have personal oversight of activities relating to the acquisition, preparation, distribution, and sale of prescription medications by pharmacy interns or supportive personnel.

"Supplying" means selling, transferring, or delivering to a patient or a patient's agent 1 or more doses of:

A nonprescription drug in the manufacturer's original container for subsequent use by the patient, or

A compressed medical gas in the manufacturer's or compressed medical gas distributor's original container for subsequent use by the patient.

"Supportive Personnel" means individuals trained to perform, under the supervision of a pharmacist, activities related to the preparation and distribution of prescription medications consistent with policy and procedures required in R4-23-403.

"Transfill" means a manufacturing process by which 1 or more compressed medical gases are transferred from a bulk container to a properly labeled container for subsequent distribution or supply.

"Wholesale distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:

Selling, purchasing, or trading a drug or offering to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this Section, "emergency medical reasons" includes transferring a prescription drug by a community or hospital pharmacy to another community or hospital pharmacy to alleviate a temporary shortage; Selling, purchasing, or trading a drug, offering to sell, purchase, or trade a drug, or dispensing a drug pursuant to a prescription;

Distributing a drug sample by a manufacturers' or distributors' representative; or

Selling, purchasing, or trading blood or blood components intended for transfusion.

"Wholesale distributor" means any one engaged in wholesale distribution of drugs, including: manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions in the amount of at least 5% of gross sales.

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS -GENERAL PROVISIONS

R4-23-704. Requirements for Medical Facilities in Industrial and Business Organizations

- A. Preface: The branch of medicine dealing with "Medical Stations" and "First Aid Stations" is known as Occupational Medicine or Industrial Medicine. The prime purpose of Occupational Medicine is to maintain by prevention, early diagnosis, rehabilitation and education, the optimal health and productivity of persons employed in business and industrial organizations. It is not meant to replace the personal physician. It is not designed to provide repeated treatments for non-occupational disorders. However, medications must occasionally be used for the following situations and therefore require Board of Pharmacy supervision:
- B. Occupational disorders: Injuries and illnesses incurred during the course of and/or as the result of the occupation.
- C. Non occupational disorders: Non-occupational disorders
 - 1. Require interim treatment until the patient can reach his personal physician.
 - Will enable employee to complete work shift or work period and thereby prevent lost time and production.
 - 3. Are of a minor nature for which a physician would ordinarily not be consulted.
- D. Qualifications: In order to qualify as a Medical Station or a First Aid Station, such stations are required to have an Arizona licensed physician responsible for its operations and the medical actions of the personnel in attendance in the unit.

- E. Registered nurse required in absence of medical practitioner: In some instances, it is not feasible for a physician to attend such stations in person at all times. In practice, some of these stations do not see the physician except on rare occasions. When a physician is not personally in attendance at the Medical Station, and medical services other than strictly first aid work are being performed, there must be an Arizona registered nurse in charge.
- First Aid Stations: In First Aid Stations which do not have an Arizona registered nurse in attendance, there should be one or more employees qualified in first aid (such as by American Red Cross or Mine Safety Appliance) available throughout the working hours.
 - (Note: It is of the utmost importance that occupational nurses exercise good judgment in the handling of medications for minor ailments. She should be careful that the symptoms and appearance of the employee are not masking signs of a more serious disorder. This holds true particularly for pains and symptoms in the chest or abdomen.).
- G. Drug laws must be observed: The Arizona State Board of Pharmacy acknowledges the establishment of Medical Stations and First Aid Stations for employees in or of industrial plants and business organizations. In order to protect the people who utilize such facilities, laws and safeguards pertaining to drugs must be observed.
- H. Regulations not intended for doctor coverage: This regulation is not intended for installations in which licensed physicians are in full-time attendance.

R4-23-706. Purchasing and Obtaining Drugs

- A. Variety and quantity of medications allowed: The variety and quantity of medications allowed at an Industrial Medical or First Aid Station must be kept to a minimum and must be only sufficient to meet the needs of the individual station.
- B. Legend drugs to be obtained from a pharmacy: Drug manufacturers and drug wholesalers are only permitted to sell to a person or firm that has a license from the Arizona State Board of Pharmacy. They can only sell or distribute legend drugs to a pharmacy licensee, either retail or hospital. Therefore, Industrial Medical Stations must obtain their legend drugs from a pharmacy.
- C. Physician must order drugs: Only the physician in charge of and responsible for the station must order the legend drugs to be used in such station. The drugs may be billed to and paid for by the company. Proprietary medicines or preparations may be obtained either as above from a pharmacy, or from other sources if a Patent and Proprietary License is obtained from the Board.
- D. Drugs must be delivered to station: Drugs must be delivered immediately upon receipt to, and properly stored in, the Medical Station or First Aid Station. Drugs cannot be stored in the company's general receiving station or warehouse.
- E. Narcoties: At a Medical Station, in order to purchase and stock any narcoties, or other controlled substances, the responsible physician must obtain a controlled substances registration from the Drug Enforcement Administration for the address of the Medical Station. All narcotic and other controlled substances supplies required for use at the Medical Station should be on the order forms issued to that address.
- F. Narcotic procedure when physician discontinues his practice at the industrial plant, he may dispose of his narcotics and other controlled substances pursuant to order forms, provided he has obtained specific approval from the Drug Enforcement Administration in which the proposed recipient is located. On the other hand, if the physician does not discontinue his practice, but merely ceases to act as the medical station's phy-

- sician, he may take the narcotic drugs and other controlled substances secured under his individual registration to his new place of business provided he obtains authorization from the Drug Enforcement Administration.
- G. Security of drugs: In a Medical Station, all drugs including proprietary medications, must be under look when the nurse or physician is not in attendance. Extra precautions should be provided for the security of narcotic drugs and other controlled substances.

R4-23-707. Limitation of Acts Permitted

- A. First Aid Stations: First aid attendants are not permitted to administer medications other than simple household remedies. First Aid Stations are only permitted to possess such simple household remedies.
- B. Registered nurse can administer, but not dispense: A registered nurse is not permitted to dispense medications; but may administer a legend or a proprietary drug, and may supply a proprietary drug in the original package of the manufacturer.
- C. Medical Stations: Medications which require handling or administration by occupational nurses fall into three categories:
 - 1. Emergency legend drugs.
 - 2. Other legend drugs.
 - 3. Proprietary drugs.
- D. Emergency legend drugs: For emergency administration only, it is permissible to store in the Medical Facility the following types of injectable medications:

Vasopressor, e.g., Epinephrin

Respiratory stimulant, e.g., Nikethamide

Narcotie, e.g., Meperidine

Antihistamin, e.g., Chlorpheniramine Maleate

Bronchodilator, e.g., Aminophyllin

Adrenal Corticosteroid

- E: Other legend drugs: Only minimal quantities of these drugs may be kept at the Medical Station. They will be administered only as ordered by the occupational physician or the employee's private physician. In each instance before an occupational nurse administered a narcotic, she must have a specific order from a physician, and phoned orders are not permissible except in true emergency situations.
- F. Legend drugs to be dispensed only by a pharmacist: Legend drugs may not be provided by the nurse for subsequent use.

 Such legend drugs, except for single unit doses administered by the nurse, must be obtained upon prescription orders for the individual employee from a physician, and dispensed by a pharmacist.
- G. Proof of Usage book: The occupational nurse will be responsible for recording in a "Proof of Usage" book the following information to account for the receipt and administration of all legend drugs:
 - 1. Date received.
 - 2. Quantity received.
 - 3. Date of administration.
 - 4. Name of patient.
 - 5. Name of medication.
 - 6. Dosage-administered.
 - 7. Name of physician responsible for the order.
- H. Record subject to inspection: The "Proof of Usage" book must be kept up to date at all times and is subject to inspection by the Board of Pharmacy Inspectors.
- Labeling of drugs: All legend drugs must be labeled in conformity with the federal Food, Drug and Cosmetic Act.
- J. Types of legend drugs: The types of medication included in this category other than emergency injectables are:
 - 1. Sedatives.

- Tranquilizers.
- 3. Anticonvulsants.
- 4. Analgesies:
- 5. Skeletal musele relaxants.
- 6. Biologicals for immunization.

R4 23 708. Proprietary Drugs

- A. Registered nurse may administer: These medications may be administered by a registered nurse for minor disorders encountered by employees during their work periods.
- B. Single dose from bulk package: A single dose of medication may be administered by the nurse from a bulk package.
- C. Prepackaged drugs: In instances where the employee should be provided more than one dose of a non-legend drug, to be subsequently used by the employee, such drugs may be supplied only in the original package of a drug manufacturer, with printed directions, warnings, etc., as required by the federal Food, Drug and Cosmetic Act. Such drugs may not be sold by the Medical Station unless a Patent and Proprietary license is obtained from the Board of Pharmacy.
- p. List of proprietary drugs: Proprietary drugs which might be used would include the following general classifications:
 - "Cold" medication:
 - Analgesies.

- Antocide
- Antidiarrhetics:
- Laxatives.
- Dysmenorrhea medications. 6-
- 7. Antiseptics.
- 8-Hydrogen peroxide.
- Ointments and salves.
- Antihistamines (non-legend).

Notice of Location and Inspection R4-23-709.

- A. Location and nurse's name to be filed with Board: A notice of the location of an Industrial Medical Station must be filed with the Arizona State Board of Pharmacy within 30 days with the name of the Arizona physician responsible for its operation, and the name of the Arizona registered nurse who will be in charge in the absence of the physician. A notice of any change of such personnel shall also be filed within 30 days with the Board of Pharmacy.
- First Aid Stations with 50 or more employees: Companies which maintain First Aid Stations for 50 or more employees shall notify the Board of the existence of such stations.
- C. Stations subject to inspection: Industrial Medical Stations and First Aid Stations are subject to inspection by Arizona State Board of Pharmacy Inspectors.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS) ADMINISTRATION

PREAMBLE

1. Sections Affected	Rulemaking Action
R9-22-101	Amend
R9-22-210	Amend
R9-22-401	Amend
R9-22-705	Amend

The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: Laws 1998, Ch. 214 Implementing statute: Laws 1998, Ch. 214

The effective date of the rules:

March 4, 1999

A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 4 A.A.R. 3047, October 16, 1998. Notice of Proposed Rulemaking: 4 A.A.R. 3721, November 13, 1998. Notice of Termination of Rulemaking: 4 A.A.R. 3791, November 13, 1998.

The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name:

Cheri Tomlinson, Federal and State Policy Administrator

Address:

AHCCCS Administration 801 East Jefferson Mail Drop 4200 Phoenix, Arizona 85034

Telephone:

(602) 417-4198

Fax:

(602) 256-6756

March 26, 1999

6. An explanation of the rule, including the agency's reasons for initiating the rule:

Four Articles in 9 A.A.C. 22 have been opened to make changes in order to bring the Articles into compliance with the Balanced Budget Act of 1997 (federal law) and Laws 1998, Ch. 214 (state law). In addition, minor changes were made to the language so it will conform with the Secretary of State's requirements.

7. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

9. The summary of the economic, small business, and consumer impact:

AHCCCS health plans will be minimally affected by the changes in rule language because health plans will be required to pay a percentage of valid, clean claims in a shorter time period. Since the time-frame requirements to notify a provider of the provider's rights regarding a reduced or denied payment for a claim was also changed, this will minimally affect health plans. Health plans will also be required to review prior authorization requests for post-stabilization services within a specified time period or risk having to pay for the service. AHCCCS providers will be nominally impacted by the changes because providers will receive payments for claims sooner. In addition, the post-stabilization authorization requirements may minimally affect them, since providers will be required to request prior authorization for services before proceeding with treatment. The Administration may be nominally impacted due to the changes in rule language because there may be a change in the method used to monitor the health plans compliance with claim payments. The Administration does not anticipate that the following changes will have an impact on the Administration, AHCCCS health plans, or providers: (1) emergency services shall be provided and paid for based on the prudent layperson standard; (2) contractors shall not employ a person with ownership of more than 5% of the contractor's equity who has been debarred or suspended by any federal agency; and (3) the Administration shall certify a contractor as a risk-bearing managed care entity. Other entities considered, but which will not be directly impacted by the changes, include AHCCCS members, other government entities, and the general public, including taxpayers.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The changes between the proposed rules and the final rules are minimal and include:

- Added the term "Administration" in R9-22-101;
- · Added cross-reference citations in R9-22-210; and
- Clarified the language pertaining to claims in R9-22-705.

11. A summary of the principal comments and the agency response to them:

The Administration received comments from 4 entities. The comments requested clarification of the federal law that underlies the changes to the rules. The Administration cross-referenced the federal law when necessary to keep the rules concise and understandable. To address some public concerns with regard to claims processing, the Administration clarified the language in that section.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable.

13. Incorporations by reference and their location in the rules:

42 CFR 438.114 as of September 29, 1998, incorporated in R9-22-210.

42 U.S.C. 1396u-2 as of August 5, 1997, incorporated in R9-22-401 and R9-22-705.

42 U.S.C. 1396b(m) as of August 5, 1997, incorporated in R9-22-401.

14. Was this rule previously adopted as an emergency rule?

Not applicable.

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS) ADMINISTRATION

ADMINISTRATION			
ARTICLE 1. DEFINITION	NS .	38. 37. "Burial plot"	R9-22-114
		39. 38. "Capital costs"	R9-22-107
Section		40. 39. "Capped fee-for-service"	R9-22-101
R9-22-101. Location of Definitions	•	41. 40. "Caretaker relative"	R9-22-114
ARTICLE 2. SCOPE OF SER	VICES	42. 41. "Case record"	R9-22-101
		43. 42. "Cash assistance"	R9-22-114
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- B. General definitions. In addition to definitions contained in A.R.S. § 36-2901, the words and phrases in this Chapter have the following meanings unless the context explicitly requires another meaning:
 - "AHCCCS" means the Arizona Health Care Cost Containment System, which is composed of the Administration, contractors, and other arrangements through which health care services are provided to an eligible person.
 - "Applicant" means a person who submits or whose representative submits, a written, signed, and dated application for AHCCCS benefits that has not been approved or denied.
 - "Application" means an official request for medical assistance made under this Chapter.
 - "Assignment" means enrollment of an eligible person with a contractor by the Administration.
 - 5. "Capped fee-for-service" means the payment mechanism by which a providers provider of care are is reimbursed upon submission of a valid elaims claim for a specific AHCCCS covered services service and equipment provided to an eligible applicants applicant. A Payments payment are is made in accordance with an upper, or capped, limit established by the Director.
 - 6. "Case record" means the file and all documents in the file that are used to establish eligibility.
 - "Categorically eligible" means a person who is eligible as defined by A.R.S. §§ 36-2901(4)(b) and 36-2934.
 - "Continuous stay" means the period of time during which an eligible person receives inpatient hospital services without interruption beginning with the date of admission and ending with the date of discharge or date of death.
 - "Contract" means a written agreement entered into between a person, an organization, or other entity and the Administration, to provide health care services to a members member under A.R.S. Title 36, Chapter 29, and these rules.
 - 10. "Contractor" means a person, an organization, or an entity that agrees through a direct contracting relationship with the Administration, to provide goods and services specified by the contract under the requirements of the contract and these rules.
 - "Contractor of record" means the an organization or an entity in which a person is enrolled for the provision of AHCCCS services.
 - "Day" means a calendar day unless otherwise specified in the text.
 - 13. "DES" means the Department of Economic Security.
 - 14. "EAC" means eligible assistance children.
 - 15. "ELIC" means eligible low income children.
 - "Eligible assistance children" means the children defined by A.R.S. § 36-2905.03(B).
 - 17. "Eligible low income children" means the children defined by A.R.S. § 36-2905.03(C) and (D).
 - 18. "Eligible applicant" means the applicant defined in A.R.S. § 36-2901(4).
 - "Enumeration" means the assignment of a specific 9digit identification number to a person by the Social Security Administration.
 - "Equity" means the county assessor full cash or market value of a resource minus valid liens, encumbrances, or both.

- 21. "Facility" means a building or portion of a building licensed or certified by the Arizona Department of Health Services as a health care institution, under A.R.S. Title 36, Chapter 4, to provide a medical services service, a nursing services service, or other health care or health-related services.
- 22. "Factor" means an organization, a collection agency, a service bureau, or a person who advances money to a provider for accounts receivable that the provider assigns, sells, or otherwise transfers, including transfers through the use of a power of attorney, to the organization, the collection agency, the service bureau, or the person that receives an added fee or a deduction of a portion of the face value of the accounts receivable in return for the advanced money. The term "factor" does not include a business representatives representative, such as a billing agents agent or an accounting firms firm described within these rules, or a health care institutions institution.
- 23. "FBR" means Federal Benefit Rate, defined in R9-22-101(B)(24).
- 24. "Federal Benefit Rate" means the maximum monthly Supplemental Security Income payment rate for an eligible person or a married couple.
- 25. "Federal emergency services program" means a program designed to provide emergency medical services covered under 42 U.S.C. 1396b(v), to treat an emergency medical condition for a categorically eligible person who is determined eligible under A.R.S. § 36-2903.03.
- 26. "FESP" means federal emergency services program.
- 27. "FQHC" means federally qualified health center.
- 28. "GSA" means a geographical service area designated by the Administration within which a contractor of record provides, directly or through a subcontract, a covered health care services service to a members member enrolled with that contractor of record.
- 29. "Hospital" means a health care institution that is licensed as a hospital by the Arizona Department of Health Services under A.R.S. Title 36, Chapter 4, Article 2, and certified as a provider under Title XVIII of the Social Security Act, as amended, or is currently determined to meet the requirements of certification.
- 30. "Indigent" means meeting eligibility criteria under A.R.S. § 11-297.
- "Inmate of a public institution" means a person defined by 42 CFR 435,1009.
- 32. "License" or "licensure" means a nontransferable authorization that is based on established standards in law, is issued by a state or a county regulatory agency or board, and allows a health care provider to render a health care service lawfully.
- 33. "Medical record" means all documents that relate to medical and behavioral health services provided to an eligible person, a physician, or other licensed practitioner of the healing arts or member and that are kept at the site of the provider.
- 34. "Medical services" means health care services provided to an eligible person by a physician, a practitioner, a dentist, or by a health professionals professional and technical personnel under the direction of a physician, a practitioner, a dentist.
- "Medically necessary" means a covered services service provided by a physician or other licensed practitioner of

the healing arts and within the scope of practice under state law to:

- Prevent disease, disability, and other adverse health conditions or their progression; or
- Prolong life.
- 36. "Medicare HMO" means a health maintenance organization that has a current contract with the Health Care Financing Administration (HCFA) for participation in the Medicare program under 42 CFR 417(L).
- 37. "MI/MN" means medically indigent and medically needy defined in A.R.S. § 36-2901(4)(a) and (c).
- 38. "Nursing facility" means a nursing facility defined in 42 U.S.C. 1396r(a).
- 39. "Noncontracting provider" means the provider defined in A.R.S. § 36-2931.
- 40. "Referral" means the process by which an eligible person is directed by a primary care provider or an attending physician to another appropriate provider or resource for diagnosis or treatment.
- "Separate property" means property defined in A.R.S. § 25-213.
- 42 "Service location" means any location at which a member obtains any health care service provided by the a contractor of record under the terms of a contract.
- 43. "Service site" means a location designated by the a contractor of record as the location at which a person is to receive health care services.
- 44. "SESP" means state emergency services program.
- 45. "S.O.B.R.A." means Section 9401 of the Sixth Omnibus Budget Reconciliation Act, 1986, amended by the Medicare Catastrophic Coverage Act of 1988, 42 U.S.C. 1396a(a)(10)(A)(ii)(IX), July 1, 1988.
- "Spouse" means the husband or wife who has entered into a contract of marriage, recognized as valid by Arizona.
- "SSA" means Social Security Administration defined in P.L. 103-296, Title I.
- 48. "SSI" means Supplemental Security Income under Title XVI of the Social Security Act, as amended.
- 49. "SSN" means social security number.
- 50. "State alien" means an unqualified alien described in A.R.S. § 36-2903.03(C).
- 51. "State emergency services program" means a program designed to provide emergency medical services identified as covered under R9-22-217 to treat an emergency medical condition for a person who is determined eligible under A.R.S. § 36-2905.05.
- 52. "Subcontract" means an agreement entered into by a contractor with any of the following:
 - A provider of health care services who agrees to furnish covered services to a members member;
 - b. A marketing organization; or
 - c. Any other organization or person who agrees to perform any administrative function or service for the a contractor specifically related to securing or fulfilling the contractor's obligations obligation to the Administration under the terms of a contract.

ARTICLE 2. SCOPE OF SERVICES

R9-22-210. Emergency Medical and Behavioral Health Services

A. Provision of and payment for emergency services. An Emergency emergency medical services service and a behavioral health emergency or crisis stabilization services may service shall be provided based on the prudent layperson standard to

- a member or <u>an</u> eligible person by <u>a</u> licensed <u>providers</u> <u>provider</u>, registered with AHCCCS to provide the services. <u>Emergency services</u> and <u>stabilization services</u> shall be provided for and paid for as specified in 42 CFR 438.114 as of <u>September 29</u>, 1998, which is incorporated by reference and on file with the Administration and the Office of the <u>Secretary of State</u>. This incorporation by reference contains no future editions or amendments.
- B. <u>Verification. The A</u> provider of emergency services shall verify eligibility and enrollment status through the Administration to determine the need for notification to a contractor for a member, or the Administration for an eligible person, and to determine the party responsible for payment of services rendered.
- C. Access. Access to an emergency room and emergency medical and behavioral health services shall be available 24 hours per day, 7 days per week in each contractor's service area. The use of an examining or a treatment rooms room shall be available when required by a physician or a practitioner for the provision of emergency services.
- D. <u>Consultation</u>. Consultation provided by a psychiatrist or a psychologist shall be covered as an emergency service if required to evaluate or stabilize an acute episode of mental illness or substance abuse.
- E. <u>Prior authorization. An Emergency emergency services service do does</u> not require prior authorization but a providers provider shall comply with the following notification requirements:
 - A Providers provider, a nonproviders nonprovider, and a noncontracting providers provider furnishing emergency services to a member shall notify the a member's contractor within 12 hours of from the time the a member presents for services;
 - A Providers provider of emergency services to for an eligible person are is not required to notify the Administration; and
 - 3. If a member's medical condition is determined not to be an emergency medical condition, as defined in Article 1 of this Chapter, the a provider shall notify the a member's contractor before initiation of treatment and follow the prior authorization requirements and protocol of the a contractor regarding treatment of the a member's non-emergent condition. Failure to provide timely notice or comply with prior authorization requirements of the a contractor constitutes cause for denial of payment.
- F. Post-stabilization services. After a member's emergent condition has been stabilized, a provider, a nonprovider, and a noncontracting provider shall request authorization from a contractor for post-stabilization services. A contractor shall pay for the post-stabilization services if:
 - 1. The service is prior authorized by a contractor; or
 - A contractor does not respond to an authorization request within the time-frame specified in 42 CFR 438.114, as of September 29, 1998, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.

ARTICLE 4. CONTRACTS, ADMINISTRATION, AND STANDARDS

R9-22-401. General

A. A Contracts contract to provide services under AHCCCS will shall be established between the Administration and a qualified providers provider of health care in conformance with

the requirements in this Article. A Contracts contract and a subcontracts subcontract entered into in accordance with according to this Article are is a public records record and shall be on file with the Administration in accordance with as specified in selected provisions of 42 and 45 CFR, as of October 1, 1995. These citations are incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.

- B. A contractor shall not knowingly have a director, an officer, a partner, or a person with ownership of more than 5% of a contractor's equity who has been debarred or suspended by any federal agency specified in 42 U.S.C. 1396u-2, as of August 5, 1997, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
- C. The Administration shall certify a contractor as a risk-bearing entity as specified in A.R.S. § 36-2903, as specified in RFP and contract, and as specified in 42 U.S.C. 1396b(m), as of August 5, 1997, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.

ARTICLE 7. STANDARDS FOR PAYMENTS

R9-22-705. Payments by Contractors

- A. Authorization. A contractor shall pay for all admissions and covered services rendered to its members if the a covered services service or an admissions admission have has been arranged by the a contractor's agents agent or an employees employee, a subcontracting providers provider, or other individuals individual acting on the a contractor's behalf and if necessary authorization has been obtained. A contractor shall not require prior authorization for a medically necessary covered services service provided during any prior period for which the a contractor is responsible. A contractor is not required to pay a claim for a covered services service that is submitted more than 6 months after the date of the service or more than 6 months after the date of eligibility posting, whichever is later, or that is submitted as a clean claim more than 12 months after the date of the service or more than 12 months after the date of eligibility posting, whichever is later. Timeliness of provider claim payment.
 - 1. A contractor shall reimburse, or provide written notice for a claim that is denied or reduced by a contractor, to a subcontracting and noncontracting providers provider for the provision of medically necessary health care services to the a contractor's members member, within the time period specified by the subcontract, between the a contractor and the a subcontracting entity, or within 60 days of receipt of a valid clean claim if a time period is not specified.
 - 2. A contractor shall provide written notice to a provider whose claim is denied or reduced by the contractor within 60 days of receipt of the claim. This notice shall include a statement describing the providers right to:
 - Grieve the contractor's rejection or reduction of the claim, and
 - b. Submit a grievance according to Article 8 of these rules.
 - Unless the subcontract specifies otherwise, a contractor shall pay valid clean claims according to 42 U.S.C. 1396u-2, as of August 5, 1997, which is incorporated by reference and on file with the Administration and the

- Office of the Secretary of State. This incorporation by reference contains no future editions or amendments and states that:
- 90% of valid clean claims shall be paid within 30 days of the date of receipt of a claim,
- b. 99% of valid clean claims shall be paid within 90 days of the date of receipt of a claim, and
- c. The remaining 1% of valid clean claims shall be paid within 12 months of the date of receipt of a claim.
- Unless the subcontract specifies otherwise, a contractor shall provide notice of a denial or a reduction of a claim for:
 - 90% of the claims within 30 days of the date of receipt of a claim.
 - 99% of the claims within 90 days of the date of receipt of a claim, and
 - c. The remaining 1% of the claims within 12 months of the date of receipt of a claim.
- A notice of denial or reduction shall include a statement describing the right to grieve the contractor's denial or reduction of a claim according to Article 8 of this Chapter.
- 3.C. Date of Claim. A contractor's date of receipt of an inpatient or an outpatient hospital claim shall be the date the claim is received by the a contractor as indicated by the date stamp on the claim, the claim reference number, or the date-specific number system assigned by the a contractor. A hospital claim shall be considered paid on the date indicated on the disbursement check. A denied hospital claim shall be considered adjudicated on the date of its denial. A Claims claim that are is pending for additional supporting documentation will receive a new dates date of receipt upon receipt of the additional documentation; however, a claims claim that are is pending for documentation other than the minimum required documentation specified in either A.R.S. § 36-2903.01(J) or A.R.S. § 36-2904(K), as applicable, will not receive a new dates date of receipt. A contractor and a hospital may, through a contract approved in accordance with as specified in R9-22-715(A), adopt a method for identifying, tracking, and adjudicating a claims claim that is different from the method described in this subsection.
- **B.D.** Payment for medically necessary outpatient <u>hospital</u> services.
 - A contractor shall reimburse a subcontracting and a noncontracting providers provider for the provision of outpatient hospital services rendered on or after March 1, 1993, at either a rate specified by a subcontract or, in absence of a subcontract, the AHCCCS hospital-specific outpatient cost-to-charge ratio multiplied by covered charges. Subcontract rates, terms, and conditions are subject to review, and approval or disapproval under A.R.S. § 36-2904(K)(1)(b) and R9-22-715.
 - A contractor shall pay for all emergency care services rendered to its a members member by a noncontracting providers provider or a nonprovider monprovider when the services:
 - a. Are rendered according to the prudent layperson standard.
 - a.b. Conform to the definitions of emergency medical and acute mental health services in Articles 1 and 12- and
 - b.c. Conform to the notification requirements in Article
- C.E. Payment for inpatient hospital services. A contractor shall reimburse an out-of-state hospital for the provision

of hospital services at negotiated discounted rates, the Arizona average cost-to-charge ratio multiplied by covered charges or, if reasonably and promptly available, the Medicaid rate that is in effect at the time a services service are is provided in the state in which the hospital is located, whichever is lowest. A contractor shall reimburse an in-state subeontractors subcontractor and a noncontracting providers provider for the provision of inpatient hospital services rendered with an admission date on or after March 1, 1993, at either a rate specified by a subcontract or, in absence of a subcontract, the prospective tiered-per-diem amount in A.R.S. § 36-2903.01 and R9-22-712. Subcontract rates, terms, and conditions are subject to review and approval or disapproval under A.R.S. § 36-2904(K)(1)(b) and R9-22-715. This subsection does not apply to a contractor participating in the pilot program described in R9-22-718.

D.F. Payment for observation days. A contractor may reimburse a subcontracting and a noncontracting providers provider for the provision of observation days at either a rate specified by a subcontract or, in the absence of a subcontract, the AHC-CCS hospital-specific outpatient cost-to-charge ratio multiplied by covered charges.

E.G. Review of hospital claims.

If a contractor and a hospital do not agree on reimbursement levels, terms, and conditions, the reimbursement levels established under A.R.S. § 36-2903.01 and R9-22-712 or R9-22-718 shall apply. In these cases, a hospital shall obtain prior authorization from the an appropriate contractor for nonemergency admissions. A contractor shall consider the medical condition of the a member, length of stay, and other factors when issuing its prior authorization. A contractor shall not require prior authorization for medically necessary services provided during any prior period for which the a contractor is responsible. If a contractor and a hospital agree to a

- subcontract, the parties shall abide by the terms of their the contract regarding utilization control activities that may include prior authorization of nonemergency admission. Failure to obtain prior authorization when it is required shall be cause for nonpayment or denial of the a claim. A hospital shall cooperate with a contractor's reasonable activities necessary to perform concurrent review and make the a hospital's medical records, specific to a member enrolled with the a contractor, available for review.
- 2. Regardless of prior authorization or concurrent review activities, all hospital claims, including outlier claims, are subject to prepayment medical review and post-payment review by the a contractor. Post-payment reviews shall be consistent with A.R.S. § 36-2903.01(O), and an erroneously paid elaims claim are is subject to recoupment. If prior authorization was given for a specific level of care, but medical review of the a claim indicates that a different level of care was appropriate, the a contractor may adjust the a claim to reflect the more appropriate level of care. An adjustment in level of care shall be effective on the date when the different level of care was medically appropriate.
- A contractor and a hospital may enter into a subcontract that includes hospital claims review criteria and procedures different from those in this subsection if the a subcontract binds both parties and meets the requirements of R9-22-715.
- F.H. Timeliness of hospital claim payment. Payment by a contractor for inpatient hospital admissions and outpatient hospital services on and after March 1, 1993, shall be subject to Laws 1993, 2nd Special Session, Ch. 6, § 29, as amended by Laws 1995, 1st Special Session, Ch. 5, § 8; Laws 1993, 2nd Special Session, Ch. 6, § 27, as amended by Laws 1995, 1st Special Session, Ch. 5, § 6; and A.R.S. § 36-2903.01(J)(6).

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 28. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS) ARIZONA LONG-TERM CARE SYSTEM

PREAMBLE

1.	Sections Affected	Rulemaking Action
	R9-28-101	Amend
	R9-28-504	Amend
	R9-28-511	Amend
	R9-28-601	Amend
	R9-28-705	Repeal
	R9-28-705	New Section

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: Laws 1998, Ch. 214 Implementing statute: Laws 1998, Ch. 214

3. The effective date of the rules:

March 4, 1999

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 4 A.A.R. 3048, October 16, 1998. Notice of Proposed Rulemaking: 4 A.A.R. 3727, November 13, 1998.

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name:

Cheri Tomlinson, Federal and State Policy Administrator

Address:

AHCCCS Administration

801 East Jefferson Mail Drop 4200

Phoenix, Arizona 85034

Telephone:

(602) 417-4198

Fax:

(602) 256-6756

6. An explanation of the rule, including the agency's reasons for initiating the rule:

Four Articles in 9 A.A.C. 28 have been opened to make changes in order to bring the Articles into compliance with the Balanced Budget Act of 1997 (federal law) and Laws 1998, Ch. 214 (state law). In addition, minor changes were made to the language so it will conform with the Secretary of State's requirements.

7. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

9. The summary of the economic, small business, and consumer impact:

It is anticipated that there will be a minimal impact on the AHCCCS Administration because it will not be required to conduct inspection of care reviews at mental hospitals and intermediate care facilities for the mentally retarded. In addition, the Administration may change the method used to monitor the health plans compliance with the new claim payment requirements which may have a nominal impact. AHCCCS program contractors will be minimally affected by the changes because program contractors will be required to pay a percentage of valid, clean claims for acute care services in a shorter time period. Since the time-frame requirements to notify a provider of the provider's rights regarding a reduced or denied payment for a claim was also changed, this will minimally affect program contractors. AHCCCS providers will be nominally impacted by the changes because providers will receive payment for valid, clean claims sooner. The addition of the terms "assisted living home" and "residential unit" will make the language consistent with state statute which changed some of the requirements for this industry. The Administration does not anticipate that the following changes will have an impact on the Administration, AHCCCS program contractors, or providers: (1) emergency services shall be provided and paid for based on the prudent layperson standard; (2) contractors shall not employ a person with ownership of more than 5% of the contractor's equity who has been debarred or suspended by and federal agency; (3) the Administration shall certify a contractor as a risk-bearing managed care entity; and (4) conflict of interest standards relating the contracts and the contract procurement process. Other entities considered, but which will not be directly impacted by the changes, include ALTCS members, other government entities, and the general public, including taxpayers.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The changes between the proposed rules and the final rules are minimal and include:

Added the term "Administration" in R9-28-101.

11. A summary of the principal comments and the agency response to them:

The Administration received comments from 2 entities. The comments requested clarification of the federal law that initiated the changes to the rules. The Administration cross-referenced the federal law when necessary to keep the rules concise and understandable. The Administration agreed to address the Balanced Budget Act requirements not covered in this rule package when more finalized guidance is received from the federal government.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable.

13. Incorporations by reference and their location in the rules:

42 U.S.C. 1396u-2 as of August 5, 1997, incorporated in R9-28-601.

42 U.S.C. 1396b(m) as of August 5, 1997, incorporated in R9-28-601.

14. Was this rule previously adopted as an emergency rule?

Not applicable.

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 28. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS) ARIZONA LONG-TERM CARE SYSTEM

ARIZONA LUNG-TERM CARE SYSTEM				
	ARTICLE 1. DEFINITION	NS	34. 35. "Developmental disability"	A.R.S. § 36-551
			35. 36. "Diagnostic services"	R9-22-102
Section			36. 37. "Disenrollment"	R9-22-117
R9-28-101.	General Definitions		37. 38. "DME"	R9-22-102
A DTICLE &	. PROGRAM CONTRACTOR	AND PROVIDER	38. 39. "Eligible person"	A.R.S. § 36-2931
AKTICLES		ANDIKOVIDER	39. 40. "Emergency medical services"	R9-22-102
	STANDARDS		40. 41. "Encounter"	R9-22-107
R9-28-504.	Standards of Participation, Lic	ensure, and Certifi-	41. 42. "Enrollment"	R9-22-117
10 10 10	cation for HCBS Providers		42. 43. "Estate"	A.R.S. § 14-1201
R9-28-511.	Quality Management/Utiliza	tion Management	43: 44. "Facility"	R9-22-101
10 20 211.	(QM/UM) Requirements		44. 45. "Factor"	R9-22-101
			45. 46. "Fair consideration"	R9-28-104
ART	ICLE 6. PROGRAM CONTR	ACTS AND	46. 47. "FBR"	R9-22-101
	PROCUREMENT PROCE	SS	47. 48. "Grievance"	R9-22-108
DO 00 (01	0		48. 49. "Guardian"	R9-22-116
R9-28-601.	General		49. 50. "HCBS" A.R.S. §§ 3	66-2931 and 36-2939
ART	TCLE 7. STANDARDS FOR P	AYMENTS	50. 51. "Home"	R9-28-101
			51. 52. "Home health services"	R9-22-101 R9-22-102
R9-28-705.	Payments by Program Contrac		52. 53. "Hospital"	R9-22-101
R9-28-705.	Payments by Program Contrac	<u>tors</u>		R9-28-101
	ARTICLE 1. DEFINITIO	NS	53. 54."ICF-MR"	R9-28-101
,	ARTICLE I. DEFRICA	110	54. <u>55.</u> "IHS"	
R9-28-101.	General Definitions		55. <u>56.</u> "IMD"	42 CFR 435.1009
A. Location	n of definitions. Definitions app	licable to this Chap-	56. 57. "Inspection of care"	R9-28-105
	ound in the following:	•	57. 58. "Institutionalized"	R9-28-104
Definiti		Section or Citation	58. 59. "JCAHO"	R9-28-101
1. "21		R9-28-104	59. <u>60.</u> "License" or "licensure"	R9-22-101
2. "21		R9-28-104	60. 61. "Medical record"	R9-22-101
3. "23		R9-28-104	61. 62."Medical services"	R9-22-101
	dministration"	A.R.S. § 36-2931	62. 63. "Medical supplies"	R9-22-102
4. <u>5.</u> "A		R9-22-101	63. 64. "Medically eligible"	R9-28-104
	ggregate"	R9-22-107	64. 65. "Medically necessary"	R9-22-101
5. U. A. 6. 7 "A	HCCCS"	R9-22-101	65. <u>66.</u> "Member"	A.R.S. § 36-2931
	HCCCS hearing officer"	R9-22-108	66. <u>67.</u> "MMMNA"	R9-28-104
		A.R.S. § 36-2932	67. <u>68.</u> "NF"	42 U.S.C. 1396r(a)
8. <u>9.</u> "A	ALTCS acute care services"	R9-28-104	68. 69. "Noncontracting provider"	A.R.S. § 36-2931
		R9-28-101	69. 70. "Occupational therapy"	R9-22-102
	'Alternative HCBS setting"	R9-22-101	70. <u>71.</u> "PAS"	R9-28-103
	'Ambulance"	R9-22-102 R9-22-108	71. <u>72.</u> "PASARR"	R9-28-103
	'Appeal"		72. 73. "Pharmaceutical service"	R9-22-102
	Bed hold"	R9-28-102	73. 74. "Physical therapy"	R9-22-102
	Behavior intervention"	R9-28-102	74. 75. "Physician"	R9-22-102
15. <u>16.</u> "	Billed charges"	R9-22-107	76. "Post-stabilization services"	42 CFR 438.114
16. <u>17.</u> "	'Capped fee-for-service"	R9-22-101	75. 77. "Practitioner"	R9-22-102
	'Case management plan"	R9-28-101	76: 78. "Primary care provider"	R9-22-102
	'Case manager"	R9-28-101	77. 79. "Primary care provider services"	R9-22-102
	'Case record"	R9-22-101	78. 80. "Prior authorization"	R9-22-102
	'Categorically eligible"	A.R.S. § 36-2934	79. 81. "Private duty nursing services"	R9-22-102
	'Certification"	R9-28-105	80. 82. "Program contractor"	A.R.S. § 36-2931
22. <u>23.</u> '		R9-28-101	81. 83. "Provider"	A.R.S. § 36-2931
	'Clean claim"	A.R.S. § 36-2904	84. "Prudent layperson standard"	42 U.S.C. 1396u-2
24, <u>25.</u> '	'Community Spouse"	R9-28-104	82. 85."Quality management"	R9-22-105
25. <u>26.</u> '	'Community Spouse Resource D	eduction" R9-28-104	83. 86."Radiology"	R9-22-102
26. <u>27.</u> '	'Comprehensive plan for delivery	of	84. 87. "Reassessment"	R9-28-103
sei	rvices"	R9-28-105	85. 88. "Redetermination"	R9-28-104
	'Contract"	R9-22-101	86. 89. "Referral"	R9-22-101
28. <u>29.</u> '	'Contractor"	R9-22-101	87. 90. "Reinsurance"	R9-22-107
29. 30.'	'County of fiscal responsibility"	R9-28-107	88. 91. "Representative"	R9-28-104
	'Covered services"	R9-22-102	89. 92. "Respiratory therapy"	R9-22-102
31. <u>32.</u> '		R9-22-107	90. 93. "Respite care"	R9-28-102
	'CSRD"	R9-28-104	91. 94. "RFP"	R9-22-105
33. <u>34.</u> '		R9-22-101	92. 95. "Room and board"	R9-28-102
<u>11</u>	•		***************************************	

93. 96. "Scope of services"	R9-22-102
94. 97. "Speech therapy"	R9-22-102
95. 98. "Spouse"	R9-28-104
9 6. 99."SSA"	P.L. 103-296, Title I
97.<u>100.</u>"SSI"	R9-22-101
98-101. "Subcontract"	R9-22-101
99.102."Utilization management"	R9-22-105
100-103."Ventilator dependent"	R9-28-102

- B. General definitions. The following words and phrases, in addition to definitions contained in A.R.S. §§ 36-2901 and 36-2931, and 9 A.A.C. 22, Article 1, have the following meanings unless the context of the Chapter explicitly requires another meaning:
 - 1. "AHCCCS" is defined in 9 A.A.C. 22, Article 1.
 - 2. "ALTCS" means the Arizona Long-Term Care System as authorized by A.R.S. § 36-2932.
 - "Alternative HCBS setting" means a living arrangement approved by the Director and licensed or certified by a regulatory agency of the state, where a member may reside and receive HCBS including:
 - For a person with a developmental disability (DD) specified in A.R.S. § 36-551:
 - Community residential setting defined in A.R.S. § 36-551;
 - ii. Group home defined in A.R.S. § 36-551;
 - State operated group home defined in A.R.S. § 36-591;
 - Family foster home defined in 6 A.A.C. 5, Article 58;
 - V. Group foster home defined in 6 A.A.C. 5, Article 59;
 - Licensed residential facility for a persons person with traumatic brain injury as specified in A.R.S. § 36-2939(C); and
 - vii. Behavioral health service agency as specified in A.R.S. § 36-2939(B)(2) and 9 A.A.C. 20, Articles 6, 7, and 8 for Levels I, II, or III;
 - For a persons person who are is elderly or physically disabled (EPD), provided the facility, setting, or institution is registered with AHCCCS:
 - i. Residential care institutions specified in A.R.S. § 36-2939(C), including adult Adult foster care homes defined in A.R.S. § 36-401; and as authorized in A.R.S. § 36-2939; and adult care homes defined in A.R.S. § 36-448, and Laws 1995, Ch. 256, amended 1997, and supportive residential living centers defined in A.R.S. § 36-1301; an assisted living home or a residential unit, as defined in A.R.S. § 36-401, and as authorized in A.R.S. § 36-2939.
 - ii. Licensed residential facility for a person with a traumatic brain injury specified in A.R.S. § 36-2939(C); and
 - Behavioral health service agency specified in A.R.S. § 36-2939(C) and 9 A.A.C. 20, Articles 6, 7, and 8 for levels I and II.
 - 4. "Case management plan" means a service plan developed by a case manager that involves the overall management of a member's or an eligible person's care, and the continued monitoring and reassessment of the member's or the eligible person's need for services.
 - 5. "Case manager" means an a person who is either a degreed social worker, a licensed registered nurse, or an a person with a minimum of 2 years of experience in providing case management services to a persons person

- who ere is elderly and physically disabled or have has developmental disabilities.
- "CFR" means Code of Federal Regulations, unless otherwise specified in this Chapter.
- 7. "Contract" is defined in 9 A.A.C. 22, Article 1.
- 8. "Contractor" is defined in 9 A.A.C. 22, Article 1.
- 9. "Day" is defined in 9 A.A.C. 22, Article 1.
- 10. "Disenrollment" is defined in 9 A.A.C. 22, Article 1.
- 11. "Eligible person" has the meaning in A.R.S. § 36-2931.
- 12. "Enrollment" is defined in 9 A.A.C. 22, Article 1.
- 13. "Facility" is defined in 9 A.A.C. 22, Article 1.
- 14. "Factor" is defined in 9 A.A.C. 22, Article 1.
- 15. "HCBS" means home and community based services defined in A.R.S. §§ 36-2931 and 36-2939.
- 16. "Home" means a residential dwelling that is owned, rented, leased, or occupied at no cost to the a member, including a house, a mobile home, an apartment, or other similar shelter. A home is not a facility, a setting, or an institution, or a portion and any of these, licensed or certified by a regulatory agency of the state as a:
 - a. Health care institution defined in A.R.S. § 36-401;
 - Residential care institution defined in A.R.S. § 36-401;
 - c. Community residential facility defined in A.R.S. § 36-551; or
 - d. Behavioral health service facility defined in 9
 A.A.C. 20, Articles 6, 7, and 8.
- 17. "Hospital" is defined in 9 A.A.C. 22, Article 1.
- "ICF-MR means an intermediate care facility for the mentally retarded and is defined in 42 CFR 435.1009 and 440.150.
- 19. "IHS" means the Indian Health Services.
- "JCAHO" means the Joint Commission on Accreditation of Healthcare Organizations.
- 21. "License" or "licensure" is defined in 9 A.A.C. 22, Article 1.
- 22. "Medical record" is defined in 9 A.A.C. 22, Article 1.
- 23. "Medical services" is defined in 9 A.A.C. 22, Article 1.
- 24. "Medically necessary" is defined in 9 A.A.C. 22, Article 1.
- 25. "Member" has the meaning in A.R.S. § 36-2931.
- "NF" means nursing facility and is defined in 9 A.A.C. 22, Article 1.
- "Noncontracting provider" has the meaning in A.R.S. § 36-2931.
- "Program contractor" has the meaning in A.R.S. § 36-2931.
- 29. "Provider" has the meaning in A.R.S. § 36-2931.
- 30. "Referral" is defined in 9 A.A.C. 22, Article 1.
- "SSA" means Social Security Administration defined in P.L. 103-296, Title I.
- 32. "SSI" is defined in 9 A.A.C. 22, Article 1.
- 33. "Subcontract" is defined in 9 A.A.C. 22, Article 1.

ARTICLE 5. PROGRAM CONTRACTOR AND PROVIDER STANDARDS

R9-28-504. Standards of Participation, Licensure, and Certification for HCBS Providers

- A. All noninstitutional long-term care providers shall be registered with the Administration and meet the requirements of the Arizona Department of Health Services' rules for licensure, if applicable.
- B. Additional qualifications:
 - A Community community residential settings setting and a group homes home for an individual with develop-

- mental disabilities shall be licensed by the appropriate regulatory agency of the state according to 6 A.A.C. 6;
- An Adult adult foster care homes home shall be certified or licensed according to 9 A.A.C. 10;
- A Home home health services service agencies agency shall be Medicare-certified and licensed according to 9 A.A.C. 10;
- An individual providing <u>a</u> homemaker services shall meet the requirements specified in contract;
- An individual providing a personal care services service shall meet the requirements specified in contract;
- An adult day health provider shall be licensed according to 9 A.A.C. 10;
- A therapy provider shall meet the <u>following</u> requirements stated below:
 - A physical therapy provider shall meet the requirements in 4 A.A.C. 24;
 - A speech therapy provider shall be certified by the American Speech, Language, and Hearing Association;
 - c. An occupational therapy provider shall meet the requirements in 4 A.A.C. 43; and
 - d. A respiratory therapy provider shall meet the requirements in 4 A.A.C. 45;
- A respite provider shall meet the requirements specified in contract;
- A hospice provider shall be Medicare_certified and licensed according to 9 A.A.C. 10;
- A provider of home delivered meal service shall comply with hygiene requirements in 9 A.A.C. 8;
- A provider of non-emergency transportation shall be licensed by the Arizona Department of Transportation, Motor Vehicle Division;
- 12. A provider of emergency transportation shall meet the licensure requirements in 9 A.A.C. 13;
- 13. A day care provider for the developmentally disabled shall meet the licensure requirements in 6 A.A.C. 6;
- A habilitation provider shall meet the requirements in A.A.C. R6-6-1523 or the therapy requirements in this Section;
- Another service provider approved by the director shall meet the requirements specified in a program contractor's contract with the Administration;
- A behavioral health provider shall have all applicable state licenses or certifications, and meet the service specifications in A.A.C. R9-22-1205;
- 17. An adult care home shall meet the requirements in 9 A.A.C. 10; and
- 17. An assisted living home or a residential unit as defined in A.R.S. § 36-401 and as authorized in A.R.S. § 36-2939.
- 18. A supportive residential living center shall meet the requirements in 9 A.A.C. 10:

R9-28-511. Quality Management/Utilization Management (QM/UM) Requirements

A. A program contractor shall:

- Comply with all requirements specified in A.A.C. R9-22-522; and
- Submit a quarterly utilization control reports report within time lines specified in contract and in-accordance with specified in 42 CFR 456 Subparts C, D, and F, December 1, 1986, incorporated by reference and on file with the Administration and the Office of the Secretary

- of State. This incorporation by reference contains no future editions or amendments.
- B. In addition to QM/UM monitoring activities specified in A.A.C. R9-22-522, the Administration shall conduct inspections of care at ICF-MR facilities, psychiatric hospitals, inpatient psychiatric facilities for individuals less than age 21 (behavioral health residential treatment centers), and institutions for mental disease (IMDs) where members reside while receiving treatment.

ARTICLE 6. PROGRAM CONTRACTS AND PROCUREMENT PROCESS

R9-28-601. General

- A. The Administration shall establish contracts to provide services under the ALTCS between itself and with qualified program contractors in conformance with the requirements in this Article.
- B. Contracts and subcontracts entered into in accordance with as specified in this Article are public records on file with the Administration.
- C. Except as otherwise provided by law, this Article applies to the expenditure of all public monies, including federal assistance monies, by the Administration for ALTCS services.
- D. The Director may conduct an investigations investigation of a persons person who have has ownership or management interests in an offeror or an affiliated organization of the offeror. The Administration shall have in effect conflict of interest safeguards with respect to an officer and an employee of the state with responsibilities relating to contracts and the contract procurement process specified in 42 U.S.C. 1396u-2, as of August 5, 1997, incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
- E. All information contained in a proposal is confidential so as to avoid disclosure of contents prejudicial to competing offerors during the process of discussions. The Administration shall open proposals for public inspection after contract award, unless upon an offeror's written request for nondisclosure, the Director makes a determination that disclosure is not in the best interests interest of the state.
- F. Failure of an offeror to supply information required by the RFP is a sufficient basis for rejecting the offeror's proposal.
- G. Disclosure by an offeror of the terms of its proposal to another offeror or to any other individual before contract award is prohibited and may be grounds for rejecting the disclosing offeror's proposal.
- H. The Administration shall retain all contract records for 5 years and dispose of these in accordance with as specified in A.R.S. § 41-2550.
- I. A contractor shall not knowingly have a director, an officer, a partner, or a person with ownership of more than 5% of a contractor's equity who has been debarred or suspended by any federal agency as specified in 42 U.S.C. 1396u-2, as of August 5, 1997, incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
- J. The Administration shall certify a contractor as a risk-bearing entity as specified in A.R.S. § 36-2932, as specified in RFP and contract, and as specified in 42 U.S.C. 1396b(m), as of August 5, 1997, incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.

ARTICLE 7. STANDARDS FOR PAYMENTS

R9 28 705. Payments by Program Contractors

- A. Program contractors shall pay for all ALTCS covered services rendered their members where such services or admissions have been arranged by their agents or employees, or providers or other individuals acting on the program contractor's behalf and for which necessary authorization has been obtained.
- B. Payment for long-term care services in institutional and home and community-based settings.
 - Program contractors shall reimburse providers and noncontracting providers for the provision of medically necessary health care-services to their members already made within the time period specified by contract between a program contractor and a provider or within 30 days of receipt of valid, clean claims if a time period is not specified in contract.
 - 2. Program—contractors—annually—shall—submit—to—the Administration—their—proposed payment methodology for-reimbursement of participating providers. All payment methods and rates of payment shall be subject to the approval of the Administration based on the reasonableness of the methods and rates. Program contractors shall use the following types or reimbursement:
 - a. The Administration's fee-for-service schedule;
 - b. Subcapitation;
 - e. Prospective payment where payment is tied to quality of care;
 - d. Volume purchase; and
 - e. Selective contracting and competitive bidding.
- C. Payment for medically necessary acute outpatient services. Program contractors shall reimburse in state providers and noncontracting providers for the provision of medically necessary outpatient services to their members, within the time period specified by contract between a program contractor and a provider or within 60 days of receipt of valid, clean claims if a time period is not specified. Reimbursement shall be made in accordance with a payment methodology set forth in subsection (B).
- D. Payment for acute hospital services and out of state hospital services.
 - Program contractors shall reimburse providers and non-contracting providers for the provision of medically necessary hospital services to their members within the time period specified in contract between a program contractor and a provider or within 60 days of a valid clean claim if a time period is not specified.
 - Program contractors shall reimburse providers and noncontracting providers for the provision of medically necessary hospital services in accordance with R9-22-705.
- E. Payment standards for emergency services. Program contractors shall pay for all emergency care services rendered their members by noncontracting providers or providers when such services:
 - Conform to the definitions of emergency medical and acute mental health services defined in A.A.C. Title 9; Chapter 22, Article 1;
 - 2. Conform to the notification requirements set forth in A.A.C. Title 9, Chapter 22, Article 2.
- F. Notification of members. Program contractors shall provide written notice to claimants whose claims are denied or

- reduced by the contractor within 30 days of disposition of such claims. This notice shall include a statement describing the provider's right to:
- Grieve the contractor's rejection or reduction of the claim; and
- 2. Submit the grievance to the Administration pursuant to Article 8 of this Chapter.
- G. Program contractors shall pay for ground or air ambulance transport in response to a 9-1-1 or other emergency response system call in accordance with A.A.C. R9-22-705.

R9-28-705. Payments by Program Contractors

- A. Authorization. A program contractor shall pay for all ALTCS covered services rendered to a member when the service or admission has been arranged by a program contractor's agent, an employee, a provider or other individual acting on a program contractor's behalf, and for which necessary authorization has been obtained.
- B. Timeliness of provider claim payment. A program contractor shall pay a claim or shall provide a notice for a denied or a reduced claim as specified in R9-22-705.
- C. Payment for a long-term care service in an institutional and a home and community based setting. A program contractor shall submit annually to the Administration, a program contractor's proposed payment methodology for reimbursement of a participating provider for long-term care services in an institutional and a home and community based setting. All payment methods and rates of payment shall be subject to the approval of the Administration based on the reasonableness of the methods and rates. A program contractor shall use the following types of reimbursement:
 - 1. The Administration's fee-for-service schedule;
 - 2. Subcapitation;
 - Prospective payment when payment is tied to quality of care;
 - Volume purchase; and
 - 5. Selective contracting and competitive bidding.
- D. Payment for in-state medically necessary acute outpatient services. A program contractor shall reimburse an in-state provider and a noncontracting provider for the provision of medically necessary outpatient services to a program contractor's member.
- E. Payment for acute inpatient hospital services and out-of-state hospital services. A program contractor shall reimburse a provider and a noncontracting provider for the provision of medically necessary inpatient hospital services to a program contractor's member.
- F. Reimbursement standards for emergency services. A program contractor shall pay for all emergency care services rendered to a program contractor's member by a noncontracting provider or a provider when the services:
 - Are rendered according to the prudent layperson standard;
 - 2. Conform to the definitions of emergency medical and acute mental health services defined in 9 A.A.C. 22.

 Article 1; and
 - 3. Conform to the notification requirements in 9 A.A.C. 22, Article 2.
- G. Transportation. A program contractor shall pay for ground or air ambulance transport in response to a 9-1-1 or other emergency response system call specified in R9-22-705.